IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

KIZZY MORALES VELAZQUEZ, et al.,

Plaintiffs,

v.

ABBOT LABORATORIES, INC.,

Defendant.

CIVIL NO. 11-1131 (FAB/CVR)

REPORT AND RECOMMENDATION

INTRODUCTION

Plaintiffs Kizzy Morales-Velázquez and Fernando Guzmán-Merly, on their own and as parents of minor F.J.G.M. (hereafter "plaintiffs") filed a complaint against defendant Abbot Laboratories, Inc. (hereafter "Abbot") based on product liability and negligence claims for a recalled infant formula manufactured by Abbot which they consider caused acute gastroenteritis to the infant which resulted in a five-days hospitalization. (Docket No. 1).

Abbot has filed a Motion for Summary Judgment, with its memorandum in support and statement of uncontested facts, submitting plaintiffs have no written discovery, no depositions and no expert report or witness. Plaintiffs only witness is the infant's treating physician Dr. Juan Vargas-Raposo (hereafter "Dr. Vargas-Raposo") who testified not knowing what caused the gastroenteritis. Thus, plaintiffs have no evidence to establish causation. (Docket Nos. 44, 45 and 46).

Plaintiffs filed their opposition to Abbot's summary judgment for they learned after the infant was discharged from the hospital that the baby formula they fed him was object

of a recall issued by Abbot for the product, Lot No. 58830T26, for being contaminated with insect pieces, larvae and/or adult insects. Plaintiffs concluded from the FDA press releases of September 27, 2010 and October 26, 2010, the milk formula was indeed contaminated. Plaintiffs admit their evidence consists of the recall campaign, plaintiffs' depositions and the deposition of the infant's treating physician, Dr. Vargas-Raposo. Plaintiffs consider this evidence as sufficient to defeat summary judgment for being plausible, within a preponderance of the evidence, the infant's gastroenteritis was caused by contamination of the baby powder milk formula at issue.(Docket No. 48).

Defendant Abbot submitted a reply memorandum of law in further support of its Motion for Summary Judgment. (Docket No. 51). Therein, Abbot reinstates plaintiffs' contention of having no need to present expert testimony. Thus, plaintiffs have conceded to defendant's argument as to their lack of evidence of causation, which standing alone, would require summary judgment. Abbot also states plaintiffs' claimed rebuttal evidence to defeat summary judgment is either inadmissible and/or non-probative. Abbot opposes plaintiffs' attempt to admit the voluntary recall notices as purported evidence of a defect in the product. Said voluntary recall should not be admitted for it is a subsequent remedial measure and, if admitted, its probative value is greatly outweighed by its potential for prejudice. Furthermore, a recall notice is insufficient to create a triable issue regarding the existence of a defect upon lack of sufficient scientific foundation as per Abbot's expert testimony.

Plaintiffs then filed a sur-reply contesting defendant's reply and prompting the Court, within its discretion, to admit the voluntary recall and FDA notices, for such notices are able to present a reasonable inference for a jury that bug infestation was the probable cause of the infant's gastroenteritis, although admittedly said medical condition is not exclusively caused by defendant's contaminated milk. (Docket No. 55).

SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Pursuant to the language of the rule, the moving party bears the two-fold burden of showing that there is "no genuine issue as to any material facts," and that he is "entitled to judgment as a matter of law." Vega-Rodríguez v. Puerto Rico Tel. Co., 110 F.3d 174, 178 (1st Cir. 1997).

After the moving party has satisfied this burden, the onus shifts to the resisting party to show that there still exists "a trial worthy issue as to some material fact." Cortés-Irizarry v. Corporación Insular, 111 F.3d 184, 187 (1st Cir. 1997). A fact is deemed "material" if it potentially could affect the outcome of the suit. *Id.* Moreover, there will only be a "genuine" or "trial worthy" issue as to such a "material fact," "if a reasonable fact-finder, examining the evidence and drawing all reasonable inferences helpful to the party resisting summary judgment, could resolve the dispute in that party's favor." *Id.*

At all times during consideration of a motion for summary judgment, the Court must examine the entire record "in the light most flattering to the non-movant and indulge all reasonable inferences in the party's favor." Maldonado-Denis v. Castillo-Rodríguez, 23 F.3d 576, 581 (1st Cir. 1994). There is "no room for credibility determinations, no room for the measured weighing of conflicting evidence such as the trial process entails, [and] no room for the judge to superimpose his own ideas of probability and likelihood . . . ." Greenburg v. Puerto Rico Mar. Shipping Auth., 835 F.2d 932, 936 (1st Cir. 1987). In fact, "[o]nly if the record, viewed in [this] manner and without regard to credibility determinations, reveals no genuine issue as to any material fact may the court enter summary judgment." Cadle Co. v. Hayes, 116 F.3d 957, 960 (1st Cir. 1997).

UNCONTESTED ISSUES OF FACTS

I. ABBOT'S UNCONTESTED ISSUES OF FACT.

A. Infant F.J.G.M.'s Conditions and Symptoms.

The infant identified as F.J.G.M. was born on July 2009 and has suffered from health problems since birth. During his first year, his pediatrician Dr. Vargas-Raposo recommended a milk formula, not at issue herein, since the infant suffered from vomiting and reflux. By July 1, 2010, when F.J.G.M. was one year old, Dr. Vargas-Raposo recommended the Similac Go & Grow formula manufactured by Abbot ["Similac"] and by September 2010 some unspecified baby food was added to the infant's diet. (Docket No. 46, Exhibit 1, plaintiff Morales' depo., pp. 16-17, 32; Exhibit 2, Report of Dr. Paul E. Hyman, Abbot's expert; Exhibit 3, Dr. Vargas-Raposo's depo., p. 39).

About a month after F.J.G.M. began consuming Similac, by July 29, 2010, he was taken to Ryder Memorial Hospital with nasal discharge and a fever, showing inflammation of throat and tonsils and was prescribed several medicines, including antibiotic. (Docket No. 46, Exhibit 3, p. 46; Exhibit 2, Dr. Hyman's report; Exhibit 4, counsel Mariana Negrón's statement, Attachment A).[1]

On August 10, 2010, F.J.G.M. visited the emergency room and was diagnosed with another upper respiratory infection. An X-ray the next day showed a viral respiratory infection and gastric distention from excessive swallowing of air. (Docket No. 46, Exhibit 3, Dr. Vargas-Raposo's depo., pp. 46-47; Exhibit 2, Dr. Hyman's report; Exhibit 4, Ryder's Hospital record, Attachment A).

On August 31, 2010, F.J.G.M. visited again the Ryder Hospital complaining of cough and was diagnosed with upper respiratory infection.

On September 10, 2010, F.J.G.M.'s parent took him to the hospital and he presented another upper respiratory infection and right otitis media. At this point, F.J.G.M.'s parents testified he also suffered from diarrhea but the admission's record stated "no" box checked for "nausea, vomiting, diarrhea." At the time, the infant was taking Amoxil, an oral antibiotic capable of causing diarrhea which had been prescribed by Dr. Vargas-Raposo for respiratory and tonsil infections. (*Id.*).

[1] Attachment A is the medical record of Ryder's Hospital organized by Atty. Mariana Negrón in chronological order as made available by plaintiffs. Attachment B is neonatologist Noel Vargas Rodriguez' medical record of infant F.J.G.M.

On September 21, 2010, another X-ray noted lung irregularities suggestive of viral infection. F.J.G.M. was prescribed antibiotics, presumably Amoxil. On September 22, 2010, the date of the Similac recall, F.J.G.M. visited Dr. Vargas-Raposo suffering from diarrhea. Antibiotic was suspended because of the fact Amoxil antibiotics gives diarrhea. (Docket No. 46, Exhibit 3, Dr. Vargas-Raposo's depo., pp. 54-56; Exhibit 2). Dr. Vargas-Raposo referred F.J.G.M. to the hospital. Upon admission, the infant was experiencing acute gastroenteritis with secondary diagnosis of otitis and moderate dehydration. F.J.G.M. was discharged from the hospital on September 25, 2010. (Docket No. 46, Exhibit 3, pp. 59, 61; Exhibit 2). According to F.J.G.M.'s mother, the diarrhea gradually improved and was gone within three (3) days from discharge. (Docket No. 46, Exhibit 1, Morales' depo., p. 51; Exhibit 2).

Over two (2) months after, his parents switched F.J.G.M.'s milk from Similac to a Gerber-brand formula, on November 27, 2010, the infant went to the emergency room with ear and throat infection. On November 30, 2010, F.J.G.M. was admitted to the hospital for five (5) days and presented very similar symptoms to his September 2010th hospitalization: gastroenteritis, dehydration, ear infection and tonsilitis. (Docket No. 46, Exhibit 3, Dr. Vargas-Raposo's depo., pp. 73, 75, 76-77; Exhibit 2; Exhibit 4, Attachment A). Another X-ray showed lung irregularities typical of a viral infection. (Docket No. 46, Exhibit 3, p. 76; Exhibit 2; Exhibit 4, Attachment A). Ms. Morales testified that in her opinion, this time F.J.G.M.'s diarrhea was caused by the antibiotics. (Docket No. 46, Exhibit 1, p. 56).

B. Abbot's Similac Product at Sturgis.

On September 25, 2010, Abbot detected warehouse beetles while performing quality testing on an unreleased batch of Similac at its Sturgis, Michigan facility. (Docket No. 46, Exhibit 6, Mathew Painter's statement ¶6). The finding was reported to Abbot's headquarters and all powder production and shipment at Sturgis were stopped. (*Id.*, ¶15). Abbot had not previously detected warehouse beetles in its Similac product despite extensive quality testings. (*Id.*, ¶¶11-14). After the beetles were detected, Abbot tested many additional units of product to evaluate the extent of the potential contamination; some 30, 486 containers from 22 separate lots of powder Similac.[2] A total of 49 beetles, larvae and/or parts –a rate of 0.16%– were detected. (*Id.*, ¶¶13-17). Regardless of the tests of virtually beetle free containers of Similac, on September 22, 2010, Abbot issued a voluntary recall of Similac brand powder products manufactured in the relevant area of Sturgis facility. Although Abbot's testing did not detect any beetles in its products before September 15, 2010, Abbot elected to recall all products manufactured in the relevant area of the plant since September 2007. Abbot made this choice because the shelf life of powder Similac is up to three (3) years and as a precaution it chose to recall all products still within their shelf life. (Docket No. 46, Exhibit 6, ¶¶6-10).

Abbot performed extensive quality testing on all powdered Similac manufactured at Sturgis before releasing products to the public. Abbot employed a prominent pest-control company to service Sturgis at a regular basis and followed all said company's

[2] The liquified Similac tested was filter and strained with a 200-micron (0.008 inch) pores.

recommendations. Both internal compliance audit in July-August 2010 and an inspection by the U.S. Food and Drug Administration (hereafter "FDA") in March 2010 found no significant issues with the Sturgis plant. (*Id.*, ¶¶ 11-15, 18-20, 21-22).

C. Similac's Product in relation to F.J.G.M.

Plaintiffs' learned about Abbot's recall from a television news show sometime during F.J.G.M.'s hospitalization of September 2010. Plaintiff Morales went to Abbot's website to check whether the can of Similac she was feeding to F.J.G.M. was part of the recall and discovered it was. Ms. Morales had about six (6) containers of Similac at her house but did not testify if these were part of the recall or if F.J.G.M. had ever consumed any of its content. While F.J.G.M. was still hospitalized, Ms. Morales' father returned all the cans of Similac to the supermarket at her behalf and the supermarket gave Ms. Morales six (6) free cans of another brand of formula in exchange. Ms. Morales called Abbot and was offered a refund check in the amount of $54.95. (Docket No. 46, Exhibit 1, Ms. Morales' depo., pp. 41-42, 45, 46, 49).

On October 26, 2010, the FDA issued an official press release announcing Abbot had worked with state and FDA officials to correct the situation and prevent its recurrence. (Docket No. 8, Exhibit C, Motion to Dismiss).

Plaintiffs never saw insects in any Similac formula they fed to F.J.G.M. After learning of the recall, plaintiffs did not examine the Similac in their possession before returning it to the supermarket. (Docket No. 46; Exhibit 1, Ms. Morales' depo., p. 50; Exhibit 5, plaintiff Guzmán's depo., p. 21).

D. Abbot's Expert Witness.

Abbot submitted an expert report by Dr. Paul E. Hyman (hereafter "Dr. Hayman"), Professor of Pediatrics at Louisiana State University and Chief of Pediatric Gastroenterology at Children's Hospital of New Orleans. Dr. Hyman has chaired and/or co-chaired two (2) working teams that developed the official criteria for diagnosing childhood functional bowel disorder. He has received awards for outstanding achievements from the American Gastroenterological Association and the International Foundation for Functional Gastrointestinal Disorders. Dr. Hyman has published over 100 peer-reviewed scientific articles, edited three books and given lectures all over the world. (Docket No. 46, Exhibit 2, Dr. Hyman's report, ¶¶1-2).

On general causation, Dr. Hyman stated that "the ingestion of *Trogoderma variable* beetle, larvae or parts has no capability of causing any injury or disorder in human infants" [the beetle identified in a very limited sample at Sturgis facility]; and that "there is no health risk from ingestion of warehouse beetles." (Docket No. 46, Exhibit 2). Dr. Hyman also indicated in his report that: a "careful search of the medical literature revealed no reports of warehouse beetle ingestion associated with illness or disease of any sort; [w]arehouse beetles ... have not been shown to carry any harmful bacteria capable of causing illness; [w]arehouse beetles ... are harmless to ingest; there is no physiological process by which consuming *Trogoderma variable* beetles could cause gastrointestinal illness." (Docket No. 46, Exhibit 2, Dr. Hyman's report ¶¶ 2, 4, 9).

On specific causation Dr. Hyman concluded that: "viral respiratory infection is the most likely underlying cause for F.J.G.M.'s alleged illness between September 20-25, 2010; [t]here is no medical evidence ... that F.J.G.M. consumed warehouse beetles; the possibility that F.J.G.M.'s illness was caused by warehouse beetles is zero". (Docket No. 46, Exhibit 2, ¶ 9).

E. Infant's Treating Physician.

Dr. Vargas-Raposo, F.J.G.M.'s pediatrician and fact witness announced by plaintiffs, is not board-certified by any medical organization, has no specialization in pediatric gastroenterology and no additional medical training since he concluded his residency in the early 1970's. (Docket No. 46, Exhibit 3, Dr. Vargas-Raposo's depo., p. 10). Dr. Vargas-Raposo has never read or heard of a child suffering gastroenteritis due to eating insects, including warehouse beetles. (*Id.*, p. 66). As to F.J.G.M., Dr. Vargas-Raposo testified he did not contemplate the infant's illness was caused by Abbot formula or by insect consumption. He listed a number of other things which, in his medical opinion, might conceivable have caused F.J.G.M.'s gastroenteritis, to wit, because of [lactose] in the milk; secondary infection the child had, ear infection; the previous taking of Amoxil, an antibiotic that can provoke diarrhea; by some other food or beverage the child consumed. (Docket No. 46, Exhibit 3, Dr. Vargas-Raposo's depo., pp. 63, 80). Finally, when Dr. Vargas-Raposo was asked whether "it's more likely than not that the child's hospitalization in September 2010 was caused by the situation of the recall of the Abbot[t] formula," he answered "I do not believe so." (*Id.*, p. 85).

II. PLAINTIFFS' UNCONTESTED ISSUES OF FACT.

Plaintiffs submitted as uncontested issues, based on the September 23, 2010 FDA Press Release and the September 22, 2010 Recall Notice of the Similac product, that Abbot has failed to show it took all adequate procedures to avoid contamination of the Similac baby powder formula. Plaintiffs propose these notices stated that "[t]here is a possibility that the infants who consume formula containing the beetles or their larvae could experience gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract". (Docket No. 48-1, Opposing Statement, ¶¶ 5, 6).

As to the treating physician Dr. Vargas-Raposo, plaintiffs refer the record of the hospital treatment was incomplete for which reason Dr. Vargas-Raposo could not testify at the deposition what treatment was ordered. Dr. Vargas-Raposo testified the infant admitted to the hospital on September 22, 2010 did not have pneumonia; he had diarrhea and vomiting, being diagnosed with acute gastroenteritis. Plaintiffs refute defendants in that Dr. Vargas-Raposo did not have elements to state the gastroenteritis was caused by antibiotics, lactose intolerance or otitis. He testified the infant's blood test and white cell counts suggested vomiting and diarrhea could have been bacteria related. (Docket No. 48-9, Dr. Vargas-Raposo's depo., pp. 60-62, 87, 94). Dr. Vargas-Raposo has taken some 200 credit hours of continuing education to keep his medical license up to date that includes medical training. (*Id.*, p. 95). Dr. Vargas-Raposo also testified he could not rule F.J.G.M.'s symptoms were 100% viral since he was receiving antibiotics for which the blood changes and the picture gets fuzzy. (*Id.*, pp. 96-97).

Plaintiff Morales testified she watched the television news related to the Similac powder milk formula recall which indicated that it was contaminated. (Docket No. 48, Exhibit 8, Ms. Morales' depo., p. 42). Plaintiffs' reports identified as Exhibits A-F [Exhibits 2-6 at Docket No. 48], refer to the FDA recall notices and Abbot's recall notice.

Plaintiffs' submit their infant child was a healthy boy. (Docket No. 48, ¶14) (Mr. Guzmán's depo., p. 23 [referring to Docket No. 46-7, defendant Abbot's Memorandum in Support of Summary Judgment]).[3]

Plaintiffs' opposition also submits that the statement of Mr. Mathew Painter, Senior Program Manager for Third Party Manufacturing in the Abbot Nutrition Supply Chain of Abbot Laboratories, indicated a presumption that the larvae had been detected in Similac powder milk formula. This conclusion is derived by plaintiffs from Painter's statement that in the rare instances that samples tested out for this kind of bacteria, the batches were promptly destroyed. (Docket No. 48, Painter's statement ¶11). Painter had also declared that 49 beetles, larvae or parts were detected in the filter sock around September 15, 2010. (*Id.*, ¶¶15, 16).

On the above issues of facts, plaintiffs argue defendant Abbot's summary judgment should be denied notwithstanding having no written discovery, no additional depositions and no medical expert's testimony except for the treating physician of the infant. Plaintiffs aver that the three (3) depositions, namely, from the two (2) plaintiffs parents of the infant

[3] Mr. Guzmán's deposition referred by plaintiffs in their opposition and statement of uncontested facts could not be located as part of plaintiffs' filings in their opposition to summary judgment, neither at Docket Nos. 48 nor Docket No. 55. However, it is part of the record before this Court in defendant Abbot's attachment and is also referred by Abbot in its reply, for which consideration of said document is proper.

and the treating physician, together with the recall notices should be sufficient to meet the preponderance criteria that acute gastritis suffered by the infant was caused by contamination of the Similac baby powder milk formula.

LEGAL ANALYSIS

In the present case, defendant Abbot's summary judgment is mainly supported by plaintiffs' lack of any expert testimony or medical evidence to support causation of F.J.G.M.'s acute gastroenteritis and resulting hospitalization of September 20, 2010 was due to ingesting contaminated milk.

When an alleged defect in a product need not be the only cause of harm to a plaintiff, it may be considered a close call whether plaintiffs' causation evidence is sufficient to survive summary judgment and liability may be found where the defect is a "substantial factor" in bringing about the harm. *See* Restatement (Second) of Torts § 431 (1965); *see* Sheehan v. The North American Marketing Corp., 610 F.3d 144 (1st Cir. 2010).

I. Plaintiffs' Lack of Expert Witness.

In regards with plaintiffs' lack of expert witness testimony, those jurisdictions which model their decisional law along Restatement lines *uniformly* hold that a strict liability claimant may demonstrate an unsafe defect through direct eyewitness observation of a product malfunction, and need not adduce expert testimony to overcome a motion for summary judgment. Although it is helpful for a plaintiff to have direct evidence of the defective condition which caused the injury or expert testimony to point to that specific defect, such evidence is not essential in a strict liability case based on § 402A (of the

Restatement (Second) of Torts), and direct observation of the malfunction itself is circumstantial evidence of a defective condition. *See* Pérez-Trujillo v. Volvo Car Corp. (Sweden), 137 F.3d 50 (1st Cir. 1998); Collazo-Santiago v. Toyota Motor Corp., 937 F.Supp. 134 (D. Puerto Rico,1996).

However, in the present case, plaintiffs have no direct observation as to any insects in the milk formula. Neither is the case a situation where the only possible cause of the infant's medical condition may have been caused because of the milk formula not even one where the preponderance of the evidence reasonably leads towards the infant's condition on September 2010 being caused by ingestion of the powder milk. To the contrary, the treating pediatrician did not even consider at the time the milk could have been the cause, but first addressed the antibiotic medication and the otitis infection. Moreover, defendant's medical expert witness testified as to the formula not being the cause of the gastroenteritis. As such, plaintiffs lack evidence of causation. If evidence is merely colorable, or is not significantly probative, summary judgment may be granted. Price v. General Motors Corp., 931 F.2d 162, 165 (1st Cir. 1991) (citing to Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249-50, 106 S.Ct. 2505, 2510-2511 (1986).

Still, it may be argued that an issue of fact in controversy exists because Mr. Guzmán, the infant's father, testified the child was healthy. This fact is rebutted by the medical records. The contradicting medical record of treatments since birth shows the infant has suffered from previous various conditions and even a subsequent one to the date at issue in the Complaint for in the month of November 2010, after defendant Abbot's milk product

had been discontinued, the infant was undergoing similar symptoms to the ones claimed to have been caused by the alleged contaminated milk on the previous month. However, we deem this credibility determination to be non-relevant for summary judgment purposes because, even if we were to consider for the sake of the argument that the infant was healthy at all times since birth, plaintiffs' lack of causation as to the defendant milk formula in the time-frame alleged in the complaint still remains non-existent.

Causation is a required element in every product liability case. As the Supreme Court of Puerto Rico has noted, a strict liability cause of action requires proof of both product defect and causation, and a manufacturer's failure to warn is a type of product defect. Rivera Santana v. Superior Pkg., Inc., 132 D.P.R. 115, 126-28 (1992). Plaintiffs refer that, under the doctrine of strict liability, a manufacturer and retailers are liable for damages if the product left their hands in a defective condition proximately causing the mishap. Still, plaintiff must establish the product was defective, the defect arose while in the control of defendant and plaintiff suffered injury thereby. This burden has not been met by plaintiffs in this case.

II. Abbott's Recall and FDA Notices - Federal Rules of Evidence 403 and 407.

In addition, plaintiffs in their sur-reply argue towards the admission of the recall and FDA notices under the Court's discretionary authority regardless that these constitute a subsequent remedial measure, for such evidence is deemed to be a party admission. (Docket No. 55). Plaintiffs' evidence has established the milk formula consumed by the

infant in this case was from the lot object of recall for which there is a possibility that it had been contaminated. Plaintiffs also aver the evidence also establishes the infant F.J.M.G. was hospitalized suffering from a medical diagnosis of acute gastroenteritis, and although this condition is not exclusively caused by contaminated milk, a reasonable jury may infer and thus find the medical condition was caused by the infant having consumed the product. Plaintiffs conclude Dr. Vargas-Raposo acknowledged being possible that the gastroenteritis was caused by the contaminated milk. (Docket No. 48, Dr. Vargas-Raposo's depo., pp. 86-87).

Abbot's response indicates plaintiffs fail to argue the need of expert testimony, thus conceding to defendant's position and making the matter waived and in defendant's favor. Insofar as the rebuttal evidence presented in plaintiffs' opposition, defendant avers the same is either inadmissible or non-probative. *See* Smith v. Robertshaw Controls Co., 410 F.3d 29 (1st Cir. 2005), the Court of Appeals affirmed the district court having granted summary judgment in the absence, among others, of an expert testimony or evidence that the product was subject to recall.[4]

Abbot's recall notice[5] of September 22, 2010 (Docket No. 48-6, Exhibit E) refers to "a proactive, voluntary recall of certain Similac-brand, powder infant formulas in the U.S., Puerto Rico, Guam and some countries in the Caribbean. Abbot is recalling these products

[4] Up to this point, with the limited evidence raised by plaintiff, the admission of the recall notices may have some weight as to plaintiffs' evidence to proof causation, for which reason the exclusion of these notices are discussed below.

[5] A recall is "a firm's removal or correction of a marketed product that the [FDA] considers to be in violation of the laws it administers and against which the agency would initiate legal action." 21 C.F.R. § 7.3 (g).

following an internal quality review, which detected the remote possibility of the presence of a small common beetle in the product produced in one production area in a single manufacturing facility. The FDA has determined that while the formula containing these beetles pose no immediate health risk, there is a possibility that infants who consume formula containing the beetles or their larvae, could experience symptoms of gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract. If these symptoms persist for more than a few days, a physician should be consulted."

The general Abbot's recall notice above only refers to a remote possibility of contamination, not as an admission of a party that it was indeed contaminated. Thus, plaintiffs still need to establish that indeed the product consumed had the defect and could cause the damage alleged. Plaintiff Morales' evidence as to the product is that she learned about the recall through an unspecified news program. Ms. Morales' testimony is considered hearsay and may, as such, not defeat summary judgment. Additionally, mere reference to "contaminated milk" in an Amended Complaint, without evidence whatsoever, does not constitute competent evidence for summary judgment.

The FDA notices of October 28, 2010, (Docket No. 48-2, Exhibit A) also refer to Abbot's voluntary recall because of possible contamination. It refers that for those who may have consumed the product it will not cause long-term health problems as well as having not received any consumer reports of illness associated with the recalled formula.[6] As to

[6] Exhibit B, FDA Notice of September 27, 2010; Exhibit C, id. Dated October 26, 2010; Exhibit D, id., make same reference and wording as above Exhibit A.

reference to insect pieces that could irritate the gastrointestinal tract, if these had been present and ingested, the warning was that it could irritate the gastrointestinal tract, causing babies to have an upset stomach or refuse food. This averment was addressed by defendant's expert witness, Dr. Hyman.

Said reference to the FDA notices cannot be evidence of causation by referring to a possibility that infants who consume the formula containing beetles or their larvae could experience gastrointestinal discomfort and refusal to eat for plaintiffs lack a sufficient scientific foundation that, even if the formula was consumed by the infant, and even if the one consumed contained the alleged beetles, it caused the acute gastroenteritis that resulted in the September 2010 hospitalization of F.J.G.M. Abbot's expert, Dr. Hyman, explained only two (2) sources on which the FDA could have relied in issuing said statement, to wit, one was back in 1967 in reference to different species of beetle and another in an article in 1991 which referred to the 1967 case report. These two (2) referenced articles were not written or published by medical doctors nor in a peer-reviewed medical journal, and as such these referred sources are regularly excluded from evidence.

Plaintiffs' treating physician, Dr. Vargas-Raposo stated lacking elements to say that the infant's illness was indeed related to the recall of Abbot's powder milk. Dr. Vargas-Raposo further indicated in his deposition not knowing or not having heard of any child suffering gastroenteritis from eating insects and that he had no medical basis for believing that consuming a warehouse beetle can, in fact, cause gastroenteritis. (Docket No. 46-3, Dr. Vargas-Raposo's depo., pp. 86-87, 66-67). In fact, Dr. Vargas-Raposo refers that one of the

causes of the gastroenteritis may be the ear infection. (Docket No. 46-3, Dr. Vargas-Raposo's depo., p. 86).

Lacking significant evidence as to causation with the absence of medical expert testimony, plaintiffs heavily rely on submitting the Abbot's recall notice and publication by FDA as to said recall of the infant formula, to which defendants have objected under federal rules of evidence.

Defendant Abbot submits the recall notices proposed by plaintiffs should not be allowed for these should be excluded under Federal Rules of Evidence 403 and 407.

Federal Rule of Evidence 403 states, "[a]lthough relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence. Still, noticing that the probative value must be substantially outweighed by the danger of unfair prejudice, a district court does have its usual discretion to exclude the evidence if, as alleged, if its probative value is substantially outweighed by the danger of unfair prejudice. *See* Bogosian v. Mercedes-Benz of North America, Inc., 104 F.3d 472, 481 (1st Cir. 1997); Raymond v. Raymond Corp., 938 F.2d 1518, 1523-24 (1st Cir. 1991). The appropriate inquiry under Rule 403, is whether the evidence results in "unfair prejudice." *See* Swajian v. General Motors Corp., 916 F.2d 31, 34 (1st Cir. 1990). " 'Unfair prejudice' ... means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." Fed.R.Evid. 403 advisory committee's note.

Under said Rule 403, courts determine whether, as a matter of law, the probative value of the relevant evidence is substantially outweighed by unfair prejudice. 22 Wright & Graham, *Federal Practice and Procedure,* §§ 5214, 5221. *See* McInnis v. AMF, Inc., 765 F.2d 240 (1st Cir.1985). The district court only has discretion to exclude evidence if the probative value is "substantially outweighed by unfair prejudice." A district court errs as a matter of law by never fully considering the probative value of the evidence and by never making a determination that the evidence would result in "unfair prejudice." The relevant inquiry is whether the probative value is "substantially outweighed by unfair prejudice." O'Brien v. Papa Gino's of America, Inc., 780 F.2d 1067, 1075 (1st Cir. 1986); Dollar v. Long Mfg. Co. N.C., Inc., 561 F.2d 613, 618 (5th Cir. 1978).

Although clearly the recall letters/notices at issue are prejudicial and maybe highly so, it is still to be determined if these be considered *substantially prejudicial*. In the absence of evidence of causation and expert testimony by plaintiff, the reliance on the recall notices to establish negligence is substantial, for as defendant submits an unreasonable and unsupportable leap is required to conclude, without more, that because F.J.G.M. consumed the product and because it was the object of a recall, the product was indeed defective and the caused the injury.

Insofar as exclusion under Federal Rule of Evidence 407, said rule prohibits admission of evidence of subsequent remedial measures taken voluntarily by a defendant.[7]

[7] The word "remedial" means "intended for a remedy or for the removal or abatement of a disease or of an evil." Webster's Third New Int'l Dictionary 1920 (1993). The Black's Law Dictionary provides for "remedial" as an action intended to correct, remove, or lessen a wrong, fault, or defect. Black's Law Dictionary 2004 (9th ed.).

Warnings at the scene of an accident or on products or sending recall notices would also constitute subsequent remedial measures.[8]

Before recall letters or notices may be admitted, a sufficient foundation should be laid wherein plaintiffs ordinarily should present expert testimony that the type of defect which is the subject of the recall existed which caused plaintiff's incident.[9] Generally, a manufacturer's recall letters are insufficient to establish that the defect which was the subject of the recall was present in the particular product that caused plaintiff's injuries. See John M. Kobayashi, *Subsequent Remedial Measures and Recall Letters and Notices*, Product Liability 1989, Warnings, Instructions and Recalls (Practicing Law Institute 1989). Although some courts have excluded a manufacturer's recall letters on relevancy grounds, the majority of courts which have excluded recall documents have done so under Rule of Evidence 407.

Federal Rule of Evidence 407 excludes subsequent remedial measures when it provides that when measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove: negligence; culpable conduct; a defect in a product or its design; or a need for a warning or

[8] David P. Leonard, The New Wigmore: Selected Rules of Limited Admissibility s. 2.6.1, Interpretation of Term "Subsequent Remedial Measures."

[9] When a plaintiff showed by independent evidence there was a defect in the product, the danger of admitting the recall letters is consider small. Calhound v. Honda Motor Co., Ltd., 738 F.2d 126 (6th Cir. 1986).

instruction.[10] A breach of warranty claim may constitute negligence or culpable conduct of the kind this federal rule prohibits. *See* Prentiss & Carlisle Co., Inc. v. Koehring-Waterous Div. of Timberjack, Inc., 972 F.2d 6 (1st Cir. 1992); Raymond, 938 F.2d at 1522 (if Rule 407 applies, it prohibits evidence of subsequent remedial measures only "to prove negligence or culpable conduct in connection with the event.").

In view of the foregoing, this Magistrate Judge recommends to the Court to deny admission of the FDA notices and Abbot's recall notices under above evidentiary rule. Still, if the Court may allow submission in evidence of said recall and FDA notices, plaintiffs would still have to meet the hurdle of causation, which it lacks through medical expert evidence or any other reliable evidence.

CONCLUSION

In view of the above discussed, it is recommended that defendant Abbot's Motion for Summary Judgment should be **GRANTED**. (Docket No. 44).

IT IS SO RECOMMENDED.

The presiding District Judge ordered the parties to file any objections to this Report and Recommendation in seven (7) CALENDAR days from the issuance of this Report and Recommendation, notwithstanding Amended Fed. R. Crim P. 59 (b)(2), term which expires on October 3, 2012. Failure to file same within the specified time waives the right to appeal this order. Henley Drilling Co. v.

[10] Rutledge v. Harley-Davidson Motor Co., 364 Fed.Appx. 103 (5th Cir. 2010) (district court did not abuse discretion in excluding recall letter under Rule 407).

McGee, 36 F.3d 143, 150-151 (1st Cir. 1994); United States v. Valencia, 792 F.2d 4 (1st Cir. 1986). *See* Paterson-Leitch Co. v. Mass. Mun. Wholesale Elec. Co., 840 F.2d 985, 991 (1st Cir. 1988) ("Systemic efficiencies would be frustrated and the magistrate's role reduced to that a mere dress rehearser if a party were allowed to feint and weave at the initial hearing, and save its knockout punch for the second round").

In San Juan, Puerto Rico, this 26th day of September of 2012.

s/CAMILLE L. VELEZ-RIVE
CAMILLE L. VELEZ-RIVE
UNITED STATES MAGISTRATE JUDGE